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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,152	03/20/2006	Svetlana Dolina	800.1020	6150

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EXAMINER	
DAVIS, ZINNA NORTHINGTON	
ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,152	DOLINA ET AL.	
	Examiner	Art Unit	
	Zinna Northington Davis	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-12,15,16 and 18* is/are pending in the application.

4a) Of the above claim(s) *16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/13/06;05/18/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4, 6, 8-12, 15, 16, and 18 are pending.

2. Claims 5, 7, 13, 14, 17, and 19-24 have been cancelled.

3. In the response filed May 18, 2009, Applicants have elected Group I, claims 1-4 and 8-11, with traverse.

4. Based upon the traversal to the Restriction Requirement, Groups II, II and IV are rejoined with the invention of Group I.

5. Claims 16 and 18 are withdrawn from consideration. These claims have not been canceled.

6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4, 6, 8-12, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making compounds wherein R' represents aminobutyrate (GABA) does not reasonably provide enablement for making compounds wherein R' represents an anti-epileptic drug, anticonvulsive

drug, neuroprotective drug, neurotransmitter or nootrope moiety as claimed. The specification does not enable any person skilled in the art to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

The Nature of the Invention

The nature of the invention is drawn to chemical compounds which are useful in the treatment of a neurological disease wherein the disease is epilepsy. In the specification, see page 17, lines 44-47.

The State of the Prior Art

The state of the prior art teaches that a pharmaceutical composition for producing anti-epileptic agents contains a pharmaceutical agent with vitamin B6 (pyridoxine chloride). See WO 01/56609 (Reference A11, cited by Applicants).

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of certain diseases, the possible treatment of all diseases is unpredictable.

Hence, in the absence of a showing of correlation between all neurological diseases claimed as capable of treatment by the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1.

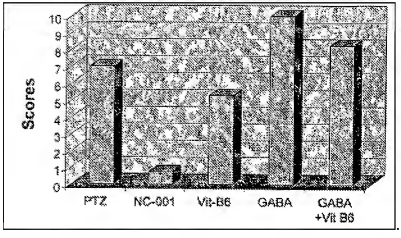
The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is that the compounds of claim 1 can treat epilepsy. The specification is silent and fails to provide guidance as to whether all neurological diseases or disorders are treatable. The specification fails to provide a correlation between all diseases and disorders.

The presence or absence of working examples

At pages 18 of the specification, the compounds N-001, PTZ, Vitamin B6, Vitamin B6 + GABA, and GABA are tested to show protection against convulsive symptoms. The figure shows that NC-001 (pyridoxine chemically linked with GABA) was superior. See Figure 1 below:



The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what listed diseases would be benefited and would furthermore then have to determine whether the claimed compounds would provide treatment of the disease. What R' compounds are included by an anti-epileptic drug, an anticonvulsive drug, a neuroprotective drug, a neurotransmitter or nootrope moiety?

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to

determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2, 6, 8-11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claims 1, 2, 8, 9, and 12, what compounds are intended by an anti-epileptic drug, an anticonvulsive drug, a neuroprotective drug, and a neurotransmitter or nootrope moiety? Clarification is appreciated.

B. At claims 1, 8, 9, and 12, it is suggested that the term "general" should be deleted.

C. Claims 6 and 10 depend upon canceled claim 5. Correction is appreciated.

D. At claims 1, 8, and 12, it is suggested that the phrase "and salts" should be written in the alternative.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 6, 8-12, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dolina et al (Reference U, cited by the Examiner).

The instantly claimed invention is disclosed. At page 37, see Table 1, and Figure 3, respectively.

13. Claims 1-3, 6, 8-12, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dakshinamurti et al (Reference V, cited by the Examiner).

The instantly claimed invention is disclosed. At page 226, see Figure 1.

14. The Information Disclosure Statements filed February 13, 2006 and May 18, 2009 have been considered.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

16. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd
07.29.2009